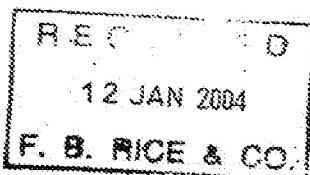


PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

F B Rice & Co
605 Darling Street
BALMAIN NSW 2041



PCT

WRITTEN OPINION
(PCT Rule 66)

| | | |
|--|---|---|
| Applicant's or agent's file reference I1566/BAL | | Date of mailing (day/month/year) - 9 JAN 2004 |
| International Application No. PCT/AU2003/01004 | International Filing Date (day/month/year) 8 August 2003 | Priority Date (day/month/year) 9 August 2002 |
| International Patent Classification (IPC) or both national classification and IPC Int. CL ⁷ A61F 11/00, A61B 17/56 | | |
| Applicant COCHLEAR LIMITED et al | | |
| <p>1. This written opinion is the first drawn by this International Preliminary Examining Authority.</p> <p>2. This opinion contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p> <p>3. The FINAL DATE by which the international preliminary examination report must be established according to Rule 69.2 is: 9 December 2004</p> <p>4. The applicant is hereby invited to reply to this opinion.</p> <p>When? See the Reply Due date indicated above. However, the Australian Patent Office will not establish the Report before the earlier of (i) a response being filed, or (ii) one month before the Final Date by which the international preliminary examination report must be established. The Report will take into account any response (including amendments) filed before the Report is established. If no response is filed by 1 month before the Final Date, the international preliminary examination report will be established on the basis of this opinion.</p> <p>Applicants wishing to have the benefit of a further opinion (if needed) before the report is established should ensure that a response is filed at least 3 months before the Final Date by which the international preliminary examination report must be established.</p> <p>How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3, for the form and the language of the amendments, see Rules 66.8 and 66.9.</p> <p>Also For an additional opportunity to submit amendments, see Rule 66.4.</p> <p>For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.</p> <p>For an informal communication with the examiner, see Rule 66.6.</p> | | |
| Name and mailing address of the IPFA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929 | Authorized Officer SUE THOMAS Telephone No. (02) 6283 2454 | |

WRITTEN OPINION

International application No.

PCT/AU2003/01004

I. Basis of the opinion

1. With regard to the elements of the international application.*

- the international application as originally filed.
- the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- the claims, pages , as originally filed,
pages , as amended under Article 19,
pages , filed with the demand,
pages , received on with the letter of
- the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- contained in the international application in printed form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description; pages
- the claims, Nos.
- the drawings, sheets/fig.

5. This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".

WRITTEN OPINION

International application No.

PCT/AU2003/01004

- V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|------------------------------------|-----|
| Novelty (N) | Claims 12-14, 17, 20-22 | YES |
| | Claims 1-11, 15, 16, 18, 19, 23-25 | NO |
| Inventive step (IS) | Claims | YES |
| | Claims 1-25 | NO |
| Industrial applicability (IA) | Claims 1-25 | YES |
| | Claims | NO |

2. Citations and explanations

1. The following documents identified in the International Search Report have been considered for the purposes of this report:

D1....US 5,906,635

D2....US 6,427,086

Novelty (N) Claims 1-11, 15, 16, 18, 19, 23-25

Claims 1-5, 7, 8, 10, 11, 18, 23: D1 discloses an implantable hearing aid device comprising a hermetically sealed component (68) mounted by screws extending through tabs (70) (figures 7, 8 and 9 and column 8 lines 60 to 62).

Claims 1-3, 5-9, 15, 16, 19, 23-25: D2 discloses an intracranial neurostimulator comprising a control module (620) with flexible flange (632) mounted into cranium by bone screws (623) (column 35 lines 5 to 16).

Inventive Step (IS) Claims 1-25

Claims 1-11, 15, 16, 18, 19, 23-25 are not novel and therefore also lack inventive step.

Claims 12-14, 17, 20-22: the features of these claims would be considered obvious to a PSA and consequently lack inventive step.